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November 12, 2004

**TO: ExaminerJohannsen (TC1600)****GROUP: 1634****FAX NUMBER: 703-872-9306****ATTORNEY DOCKET NO.: SJ-0029****SERIAL NO.: 09/974,619****FILED: December 14, 2000****NUMBER OF PAGES: 27**

**MESSAGE:** Attached please find copy of Notice of Non-Compliant Amendment (37 CFR 1.121); the entire "Amendments to the claims" section of applicant's amendment document in response to the Office Action filed July 20, 2004; and Certificate of Transmission by Facsimile.

**Respectfully submitted,****Kathleen A. Tyrrell, Registration No. 38,350****URGENT! PLEASE DELIVER IMMEDIATELY UPON RECEIPT. THANK YOU!**

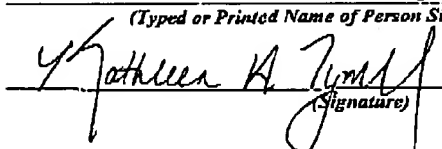
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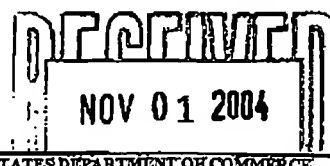
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<b>CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)</b> Applicant(s): Schuetz et al.			Docket No. SJ-0029
Application No. 09/974,619	Filing Date October 19, 2001	Examiner Johannsen, Diana B.	Group Art Unit 1634
Invention: Genotyping Assay to Predict CYP3A5 Phenotype			
<div style="text-align: right;"><b>RECEIVED</b> <b>CENTRAL FAX CENTER</b> <b>NOV 12 2004</b></div> <p>I hereby certify that this <u>Notice of Non-Compliant Amendment (37 CFR 1.121)</u> <small>(Identify type of correspondence)</small> is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No: <u>703-872-9306</u>) on <u>November 12, 2004</u> <small>(Date)</small></p> <div style="text-align: right;"><p>Kathleen A. Tyrrell <small>(Typed or Printed Name of Person Signing Certificate)</small></p> <small>(Signature)</small></div> <p style="text-align: center;">Note: Each paper must have its own certificate of mailing.</p>			



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,619	10/10/2001	Eric Schuetz	44158/244344	8446

7590

10/25/2004

Jane Massey Licata  
 Licata & Tyrrell P.C.  
 66 E. Main Street  
 Marlton, NJ 08053

Docket System  
 Status Report  
 Docket Book

*sg-0029*

EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 10/25/2004

*11/25/04*

Please find below and/or attached an Office communication concerning this application or proceeding.



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Paper No.

## Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 7/15/04 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003 (see 68 Fed. Reg. 38611, Jun. 30, 2003). In order for the amendment document to be compliant, correction of the following item(s) is required. Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted. 37 CFR 1.121(h).

## THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other \_\_\_\_\_
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other \_\_\_\_\_
- ☐ 3. Amendments to the drawings: \_\_\_\_\_
- ☒ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all claims (including withdrawn claims)
  - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified.
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: "Previously presented" claims in correctly identified as "new"

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/procnotice/office/lyer.pdf>.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given **ONE MONTH** from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and this **ONE MONTH** time limit is not extendable.

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION** (including a submission for an RCE), and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a **TIME PERIOD** of **ONE MONTH** from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action. The period for response to a final rejection continues to run from the date set in the final rejection, and is not affected by the non-compliant status of the amendment.

Legal Instruments Examiner (LIE)

Telephone No.

DIANA JOHANNSEN

571/272-0744

Rev. 10/03

PRIMARY EXAMINER

Application/Control Number: 09/974,619

Page 2

Art Unit: 1634

1. The amendment to the claims filed on July 20, 2004 does not comply with the requirements of 37 CFR 1.121(c) because applicant's amendment does not indicate all changes relative to the immediate prior version of the claims by the required markings, as set forth in 37 CFR 1.121(c)(2). For example, in claim 1, at line 25 of item (c) of the claim, Applicant has deleted a recitation of "G" and inserted a recitation of "U"; however, neither the deletion nor the insertion are indicated by the required markings.

Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall

Application/Control Number: 09/974,619  
Art Unit: 1634

Page 3

include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

2. Since the reply filed on July 20, 2004 appears to be *bona fide*, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance with 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

3. Applicant is requested to review all of the amended claims to ensure that Applicant's claim set includes all of the required markings. It is noted that only the corrected section of the non-compliant amendment (in the instant case, the listing of the claims) must be resubmitted (in its entirety).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

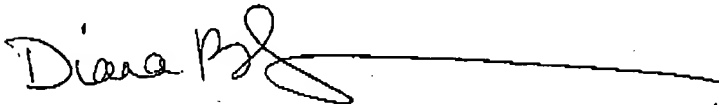
Application/Control Number: 09/974,619  
Art Unit: 1634

Page 4

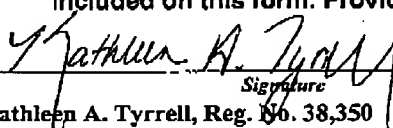
571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen  
Primary Examiner  
October 20, 2004

<b>AMENDMENT TRANSMITTAL LETTER (Small Entity)</b>				Docket No. <b>SJ-0029</b>	
Applicant(s): <b>Schuetz et al.</b>					
Application No. <b>09/974,619</b>	Filing Date <b>October 19, 2001</b>	Examiner <b>Johannsen, Diana B.</b>	Customer No. <b>31949</b>	Group Art Unit <b>1634</b>	Confirmation No. <b>8446</b>
Invention: <b>Genotyping Assay to Predict CPY3A5 Phenotype</b>					
<b>COMMISSIONER FOR PATENTS:</b>					
Transmitted herewith is an amendment in the above-identified application.				<b>RECEIVED</b> <b>CENTRAL FAX CENTER</b>  <b>NOV 12 2004</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27					
The fee has been calculated and is transmitted as shown below.					
<b>CLAIMS AS AMENDED</b>					
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	41 -	48 =	0 x	\$9.00	\$0.00
INDEP. CLAIMS	8 -	12 =	0 x	\$44.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
<b>TOTAL ADDITIONAL FEE FOR THIS AMENDMENT</b>					<b>\$0.00</b>
<input checked="" type="checkbox"/> No additional fee is required for amendment. <input type="checkbox"/> Please charge Deposit Account No. _____ in the amount of _____ <input type="checkbox"/> A check in the amount of _____ to cover the filing fee is enclosed. <input checked="" type="checkbox"/> The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. <b>50-1619</b> <input checked="" type="checkbox"/> Any additional filing fees required under 37 C.F.R. 1.16. <input checked="" type="checkbox"/> Any patent application processing fees under 37 CFR 1.17. <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
<b>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</b>					
 Kathleen A. Tyrrell, Reg. No. 38,350			Dated: November 12, 2004		
Licata & Tyrrell P.C. 66 East Main Street Marlton, New Jersey 08053 Tel : 856-810-1515 Fax: 856-810-1454			I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ (Date)		
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